

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
8 December 2005 (08.12.2005)

PCT

(10) International Publication Number
WO 2005/115507 A1

(51) International Patent Classification⁷: **A61M 5/20, 5/32**

(52) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AI, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CI, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PI, PT, RO, RU, SC, SD, SE, SG, SK, SI, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:
PCT/GB2005/002108

(22) International Filing Date: 27 May 2005 (27.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0412053.1 28 May 2004 (28.05.2004) GB

(71) Applicant (for all designated States except US): CILAG AG INTERNATIONAL [CH/CH]; Landis & Gyrstrasse 1, CH-6300 Zug (CH).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **HARRISON, Nigel** [GB/GB]; PA Consulting Group, Cambridge Technology Centre, Meibourn, Hertfordshire SG8 6DP (GB).

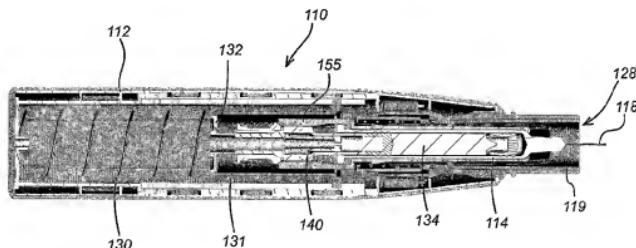
(74) Agents: TUNSTALL, Christopher, Stephen et al.; Carpmaels & Ransford, 43-45 Bloomsbury Square, London WC1A 2RA (GB).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TI, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, MI, MR, NE, SN, TD, TG).

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INJECTION DEVICE



(57) Abstract: An injection device (110) is described having a housing (112) that receives a syringe (114) having a needle (118), wherein the syringe is supported in a syringe carrier (150). The syringe and syringe carrier are biased by a return spring (126) from an extended position in which the needle (118) extends from the housing (112) through an exit aperture (128) to a retracted position in which it does not. A drive spring (130) acts via a drive to advance the syringe from its retracted position to its extended position and discharge its contents through the needle and a return spring, brought into play when the drive has reached a nominal return position, restores the syringe to its retracted position.

WO 2005/115507 A1

INJECTION DEVICE**BACKGROUND TECHNOLOGY**

5 The present invention relates to an injection device of the type that receives a syringe, extends it, discharges its contents and then retracts it automatically. Devices of this general description are shown in WO 95/35126 and EP-A-0 516 473 and tend to employ a drive spring and some form of release mechanism that releases the syringe from the influence of the drive spring once its contents are supposed to have been discharged, to allow it to be
10 retracted by a return spring.

Often, such injection devices are required to work with glass pre-filled syringes that were originally designed for manual use. Such glass syringes have a flange at their base to allow a user to grip the syringe. The substantial force produced by the drive spring is applied to
15 the piston of the syringe. This force is transferred to the housing and return spring, via the flange. The flanges are not precision moulded and consequently have low manufacturing tolerances. They are not sufficiently flat or consistent to be used as a satisfactory support means for the syringe through which the force of the drive spring is transferred to the housing and return spring.

20 In practice, these flanges have been seen to fail when the drive spring is employed and the force produced by the drive spring is applied, via the piston of the syringe, to the flange. In particular, these flanges have been seen to break off from the syringe, resulting in the syringe body being propelled from the front of the injection device, and the whole needle
25 being inserted into the user's body. Consequently, when the injection device is taken away from the user's body, a full, broken syringe is left dangling from the user's body. This is clearly dangerous because the user is left with a broken syringe, and consequently broken glass, dangling from their body. The user is also left without having had their correct dose of drug. Such a syringe failure is also, of course, unpleasant for any user, particularly those
30 that are squeamish.

SUMMARY OF THE INVENTION

The injection devices of the present invention are designed to deal with these problems.

5 An injection device according to the present invention comprises:

a housing adapted to receive a syringe having a relatively wide reservoir portion and a relatively narrow discharge nozzle, so that the syringe is movable between a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle extends from the housing through an exit

10 aperture;

a drive that acts upon the syringe to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle; and

a syringe carrier for carrying the syringe as it is advanced and restraining its advancement beyond its extended position, wherein the syringe carrier is adapted to

15 support the syringe between the reservoir portion and the discharge nozzle.

The syringe carrier may provide an interface between the syringe and the housing.

The syringe carrier may comprise an annular collet having an internal diameter that is
20 smaller than an outer diameter of the reservoir portion of the syringe. The annular collet may be adapted to support the syringe between the reservoir portion and the discharge nozzle. The annular collet may be a split annular collet.

The syringe carrier may further comprise a sheath for surrounding the reservoir portion of
25 the syringe, having a first internal diameter along its length, and further having a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted to support the syringe between the reservoir portion and the discharge nozzle. The sheath may be split.

30 By supporting the syringe close to its first end with the syringe carrier, any force applied to the housing by the drive spring is transferred to the housing via the first end of the syringe. No force is transferred via any flange of the syringe. The first end of the syringe has been found to be stronger than the flange of the syringe, and to be less prone to failure. In

particular, tests have been carried out in which impact loads have been applied to the piston of a filled syringe. In tests where the syringe was supported in a rubber buffer under the flange, a mass of 1.6 kg dropped from 50mm would almost always result in a broken syringe. In tests where the syringe was supported on a conical collet under the end of the

5 syringe nearest to the discharge nozzle, the syringes would almost always withstand the same mass being dropped from 75mm. Generally, when the syringe was supported on a conical collet under the end of the syringe nearest to the discharge nozzle, multiple impacts were required for failure.

10 By surrounding the syringe with the syringe carrier close to its first end, if the syringe does fail, it will not be propelled from the end of the device because it will not be able to fit through the part of the syringe carrier which has a reduced diameter.

By providing a sheath that is split, the syringe can be inserted into the syringe carrier

15 through the split of the sheath. Generally, syringes are provided with a boot which covers the discharge nozzle. The boot is generally of larger diameter than the body of the syringe. By providing a split sheath, the syringe can be inserted into the sheath, without having to remove the boot from the syringe. This is advantageous because it is a requirement that the

20 discharge nozzle of the syringe remains sterile for as long as possible before the injection device is used.

The injection device may further comprise means for biasing the syringe from its extended position to its retracted position and a support for carrying the means for biasing the syringe. The syringe carrier may further comprise means for bearing against the support.

25 The means for bearing may comprise a portion having an external diameter which is greater than the external diameter of any portion of the syringe carrier situated between the means for bearing and the discharge nozzle.

The syringe carrier may further comprise a ramped surface, and the support may further

30 comprise a corresponding locking surface, wherein the ramped surface is adapted to communicate with the locking surface so as to lock the syringe carrier relative to the support.

The injection device may further comprise a drive element and the syringe carrier may further comprise an annular portion which is adapted to act as part of a release mechanism and couple with the drive element in order to disconnect the drive element from the drive and allow the return spring to move the syringe from its extended position to its retracted
5 position.

BRIEF DESCRIPTION OF THE DRAWINGS

10 The invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 shows a cross-sectional view of an injection device according to the present invention; and

15

Figure 2 shows an enlarged part of the injection device shown in figure 1.

Figure 3 shows a perspective view of a syringe carrier for use in the present invention from a first direction;

20

Figure 4 shows a perspective view of the syringe carrier of figure 3 from a second direction.

25 DETAILED DESCRIPTION

Figures 1 and 2 show an injection device 110, having an injection device housing 112. The end of the housing 112 has an exit aperture 128, through which the end of a sleeve 119 can emerge.

30

The housing 112 contains a hypodermic syringe 114 of conventional type, including a syringe body 116 defining a reservoir and terminating at one end in a hypodermic needle 118 and at the other in a flange 120. The syringe body 116 is of substantially constant

- 5 -

diameter along the length of the reservoir, and is of significantly smaller diameter close to the end of the syringe which terminates in the hypodermic needle. A drive element 134 acts through the bung of the syringe to discharge the contents of the syringe 114 through the needle 118.. This drive element 134 constrains a drug 124 to be administered within the 5 reservoir defined by syringe body 116. Whilst the syringe illustrated is of hypodermic type, this need not necessarily be so. Transcutaneous or ballistic dermal and subcutaneous syringes may also be used with the injection device of the present invention.

As illustrated, the syringe is housed within a syringe carrier 150. The syringe carrier is best 10 seen in figures 3 and 4. The syringe carrier 150 has a first end 151 which has a reduced diameter. The first end 151 of the syringe carrier supports the end of the syringe 114 nearest to the hypodermic needle. Close to the other end of the syringe carrier 150, are provided a pair of ramped projections 152. The pair of ramped projections 152 communicate with a corresponding pair of locking apertures on a return spring support 160 15 so that the syringe carrier 150 cannot move relative to the return spring support 160. The syringe carrier 150 also comprises a bearing surface 153 close to its second end, against which a corresponding bearing surface of the return spring support 160 is biased by a return spring 126. The return spring 126, via the return spring support 160 and the syringe carrier 150 biases the syringe 114 from an extended position in which the needle 118 extends 20 from the aperture 128 in the housing 112 to a retracted position in which the needle 118 is contained within the housing 112.

The syringe carrier 150 comprises a sheath 154 which is split along its length so that the 25 syringe 114 can be clipped into the syringe carrier 150. The syringe 114 is provided with a boot (not shown). By providing a syringe carrier 150 in the form of a split sheath 154, the syringe 114 can be inserted into the syringe carrier 150 and in turn into the injection device 110 without having to remove the boot from the syringe 114. Furthermore, if the syringe were to fail or break, the sheath 154, which substantially surrounds the syringe 114 along 30 its length, would contain the broken pieces of syringe and reduce the likelihood of them escaping from the injection device.

The housing is further provided with a resilient latch member 161 that is biased into a position in which it engages a locking surface 163 on the return spring support 160. Before

engaging the locking surface 163, the latch member 161 also extends through a latch opening 165 in the sleeve 119. The latch member 161 includes a ramped surface 167 against which an edge of the latch opening 165 acts in the manner of a cam acting on a cam follower.

5

The housing also includes an actuator, and a drive which here takes the form of a compression drive spring 130. Drive from the drive spring 130 is transmitted via a multi-component drive to the piston of the syringe 114 to advance the syringe from its retracted position to its extended position and discharge its contents through the needle 118. The 10 drive accomplishes this task by acting directly on the drug 124 and the syringe 114. Static friction between the drive element 134 and the syringe body 116 initially ensures that they advance together, until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion.

15 The multi-component drive between the drive spring 130 and the syringe 114 consists of three principal components. A drive sleeve 131 takes drive from the drive spring 130 and transmits it to a first drive element 132. This in turn transmits drive to the drive element 134 already mentioned.

20 The drive element 132 includes a hollow stem 140, the inner cavity of which forms a collection chamber 142 in communication with a vent 144 that extends from the collection chamber through the end of the stem 140. The second drive element 134 includes a blind bore 146 that is open at one end to receive the stem 140 and closed at the other. As can be seen, the bore 146 and the stem 140 define a fluid reservoir 148, within which a damping 25 fluid is contained.

A trigger (not shown) is provided on the housing 112 remote from the exit aperture 128. The trigger, when operated, serves to decouple the drive sleeve 131 from the housing 112, allowing it to move relative to the housing 112 under the influence of the drive spring 130. 30 The operation of the device is then as follows.

Initially, the return spring carrier 152, and consequently the syringe carrier 150 and syringe 114, are prevented from movement by the resilient latch member 161. By moving the

sleeve 119 in a direction into the housing 112, the edge of the latch opening 165 is brought into contact with the ramped surface 167 of the latch member 161, causing the latch member 161 to move outwards and thus to disengage from the return spring support 160. Once the latch member 161 has disengaged from the locking surface 163, the syringe is
5 free to move.

The actuator is then depressed and the drive spring 130 is released. The drive spring 130 moves the drive sleeve 131, the drive sleeve 131 moves the first drive element 132 and the first drive element 132 moves the second drive element 134. The second drive element 134
10 moves and, by virtue of static friction and hydrostatic forces acting through the drug 124 to be administered, moves the syringe body 114 against the action of the return spring 126. The syringe body 114 moves the syringe carrier 150, which in turn moves the return spring support 160 and compresses the return spring 126. The hypodermic needle 118 emerges from the exit aperture 128 of the housing 112. This continues until the return spring 126
15 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion. Because the static friction between the second drive element 134 and the syringe body 116 and the hydrostatic forces acting through the drug 124 to be administered are not sufficient to resist the full drive force developed by the drive spring 130, at this point the second drive element 134 begins to move within the syringe body 116 and the
20 drug 124 begins to be discharged. Dynamic friction between the second drive element 134 and the syringe body 116 and hydrostatic and hydrodynamic forces now acting through the drug 124 to be administered are, however, sufficient to retain the return spring 126 in its compressed state, so the hypodermic needle 118 remains extended.

25 Before the second drive element 134 reaches the end of its travel within the syringe body 116, so before the contents of the syringe have fully discharged, flexible latch arms linking the first and second drive elements 132, 134 reach a constriction within the housing 112 formed by an annular portion 155 at the end of the syringe carrier which is nearest to the flange 120 of the syringe 114. The constriction moves the flexible latch arms to a position
30 so that they no longer couple the first drive element 132 to the second drive element 134. Once this happens, the first drive element 132 acts no longer on the second drive element 134, allowing the first drive element 132 to move relative to the second drive element 134.

Because the damping fluid is contained within a reservoir 148 defined between the end of the first drive element 132 and the blind bore 146 in the second drive element 134, the volume of the reservoir 146 will tend to decrease as the first drive element 132 moves relative to the second drive element 134 when the former is acted upon by the drive spring 130. As the reservoir 148 collapses, damping fluid is forced through the vent 144 into the collection chamber 142. Thus, once the flexible latch arms have been released, some of the force exerted by the drive spring 130 does work on the damping fluid, causing it to flow through the constriction formed by the vent 144; the remainder acts hydrostatically through the fluid and through friction between the first and second drive elements 132, 134, thence via the second drive element 134. Consequently, the second drive element 134 continues to move within the syringe body 116 and the drug 124 continues to be discharged. Losses associated with the flow of the damping fluid do not attenuate the force acting on the body of the syringe to a great extent. Thus, the return spring 126 remains compressed and the hypodermic needle remains extended.

15

After a time, the second drive element 134 completes its travel within the syringe body 116 and can go no further. At this point, the contents of the syringe 114 are completely discharged and the force exerted by the drive spring 130 acts to retain the second drive element 134 in its terminal position and to continue to cause the damping fluid to flow though the vent 144, allowing the first drive element 132 to continue its movement.

Before the reservoir 148 of fluid is exhausted, flexible latch arms linking the drive sleeve 131 with the first drive element 132 reach another constriction within the housing 112. The constriction moves the flexible latch arms so that they no longer couple the drive sleeve 131 to the first drive element 132. Once this happens, the drive sleeve 131 acts no longer on the first drive element 132, allowing them to move relative each other. At this point, the forces developed by the drive spring 130 are no longer being transmitted to the syringe 114. The only force acting on the syringe will be the return force from the return spring 126 which acts on the end of the syringe 114 nearest to the needle 118 via the return spring 160 and the syringe carrier 150. Consequently, the syringe is returned to its retracted position and the injection cycle is complete.

CLAIMS

1. An injection device comprising:

a housing adapted to receive a syringe having a relatively wide reservoir portion
5 and a relatively narrow discharge nozzle, so that the syringe is movable between a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle extends from the housing through an exit aperture;

10 a drive that acts upon the syringe to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle; and

a syringe carrier for carrying the syringe as it is advanced and restraining its advancement beyond its extended position, wherein the syringe carrier is adapted to support the syringe between the reservoir portion and the discharge nozzle.

15 2. An injection device according to claim 1, wherein the syringe carrier provides an interface between the syringe and the housing.

3. An injection device according to claim 1 or claim 2 wherein the syringe carrier comprises an annular collet having an internal diameter that is smaller than an outer 20 diameter of the reservoir portion of the syringe, wherein the annular collet is adapted to support the syringe between the reservoir portion and the discharge nozzle.

4. An injection device according to claim 3 wherein the annular collet is a split annular collet.

25

5. An injection device according to any preceding claim in which the syringe carrier comprises a sheath for surrounding the reservoir portion of the syringe, wherein the sheath has a first internal diameter along its length, and a first end with a second internal diameter which is smaller than the first internal diameter so that the first end of the sheath is adapted 30 to support the syringe between the reservoir portion and the discharge nozzle.

6. An injection device according to claim 5 in which the sheath is split along its length.

7. An injection device according to any preceding claim further comprising means for biasing the syringe from its extended position to its retracted position.
- 5 8. An injection device according to claim 7, further comprising a support for carrying the means for biasing the syringe.
9. An injection device according to claim 8, wherein the syringe carrier further comprises means for bearing against the support.
- 10 10. An injection device according to claim 9 in which the means for bearing comprises a portion having an external diameter which is greater than the external diameter of any portion of the syringe carrier situated between the means for bearing and the discharge nozzle.
- 15 11. An injection device according to any of claims 8 to 10 in which the syringe carrier further comprises a ramped surface, and the support further comprises a corresponding locking surface, wherein the ramped surface is adapted to communicate with the locking surface so as to lock the syringe carrier relative to the support.
- 20 12. An injection device according to any of claims 7 to 11, further comprising a drive element, wherein the syringe carrier further comprises an annular portion which is adapted to act as part of a release mechanism and couple with the drive element in order to disconnect the drive element from the drive.
- 25 13. An injection device substantially as hereinbefore described with reference to and as shown in the attached drawings.

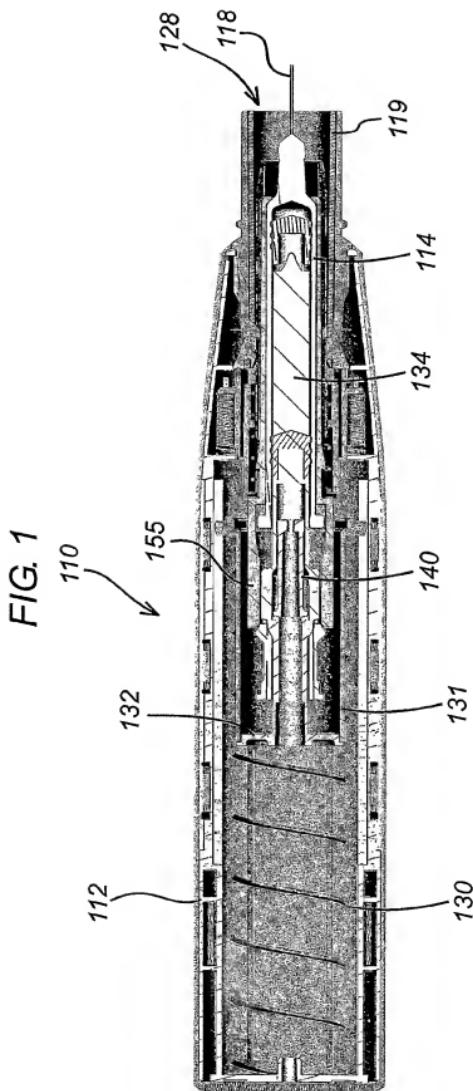
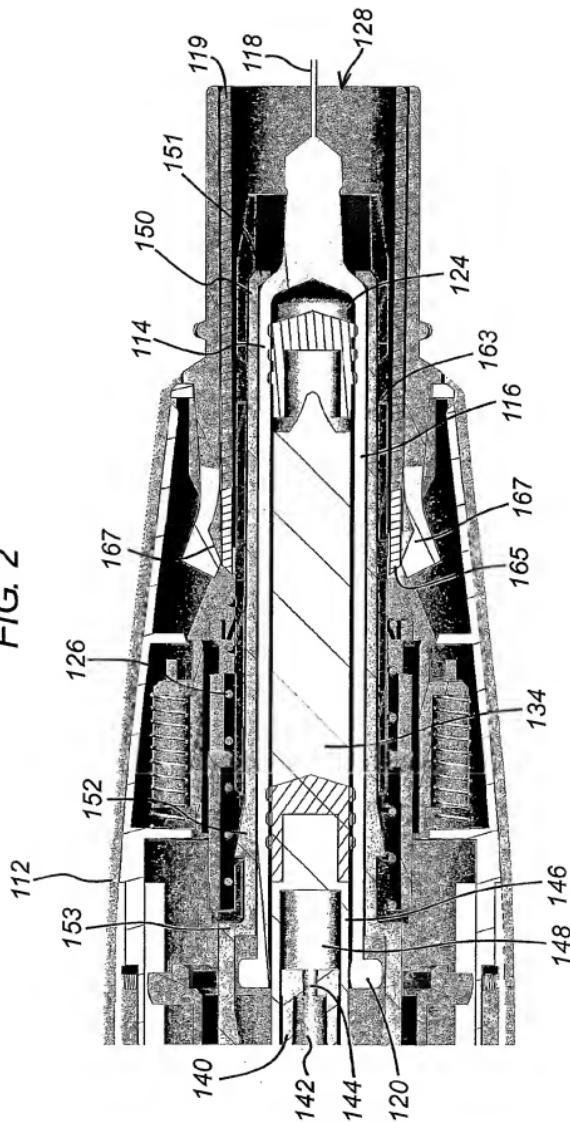
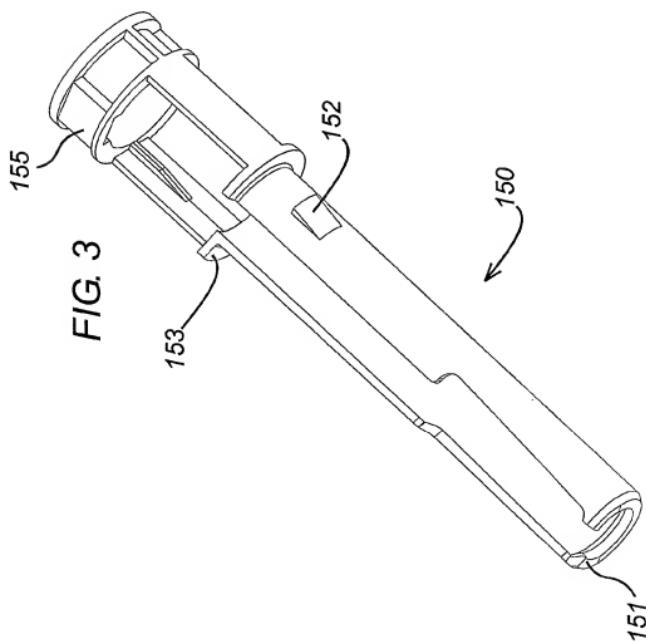
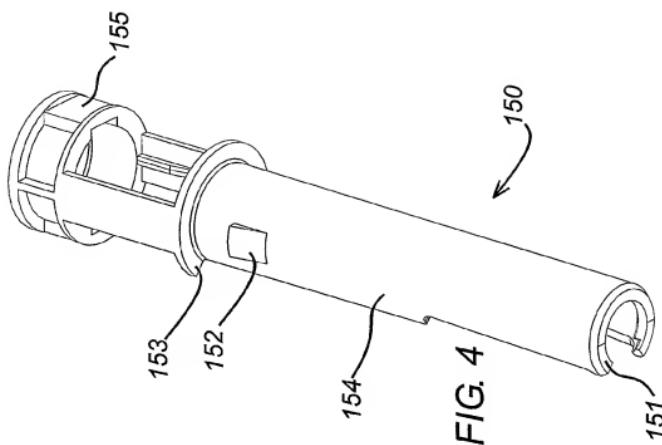


FIG. 2





INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/GB2005/002108

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/20 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ^a	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	US 2005/020979 A1 (WESTBYE LARS TOMMY ET AL) 27 January 2005 (2005-01-27) abstract; figures 2,5 -----	1-12
X	US 6 613 022 B1 (DOYLE MARK CHRISTOPHER) 2 September 2003 (2003-09-02) abstract; figures -----	1-12
X	US 6 454 743 B1 (WEBER WILFRID) 24 September 2002 (2002-09-24) abstract; figure 1 -----	4
X	US 6 203 530 B1 (STEWART, SR, EDWARD) 20 March 2001 (2001-03-20) abstract; figures -----	1
A	-----	2-12
	-----	-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

^b Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority (claim) or document used to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

26 August 2005

Date of mailing of the international search report

06/09/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5616 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ehrsam, F

INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/GB2005/002108

C./Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 599 309 A (MARSHALL ET AL) 4 February 1997 (1997-02-04)	1
A	-----	2-12
X	US 6 544 234 B1 (GABRIEL JOCHEN) 8 April 2003 (2003-04-08)	1
A	abstract; figures -----	2-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

In	nternational Application No
PCT/GB2005/002108	

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 2005020979	A1	27-01-2005	WO	2005009520 A1		03-02-2005
US 6613022	B1	02-09-2003	US	6623459 B1		23-09-2003
			CA	2407739 A1		15-11-2001
			EP	1284769 A2		26-02-2003
			JP	2003532500 T		05-11-2003
			WO	0185239 A2		15-11-2001
			US	2005101917 A1		12-05-2005
US 6454743	B1	24-09-2002	DE	19819409 A1		11-11-1999
			AT	222129 T		15-08-2002
			AU	741039 B2		22-11-2001
			AU	4600499 A		23-11-1999
			CA	2326359 A1		11-11-1999
			WO	9956805 A1		11-11-1999
			DE	59902348 D1		19-09-2002
			DK	1075292 T3		16-12-2002
			EP	1075292 A1		14-02-2001
			ES	2182540 T3		01-03-2003
			JP	2002513647 T		14-05-2002
			NO	20005326 A		23-10-2000
			PT	1075292 T		31-12-2002
			ZA	200006033 A		10-08-2001
US 6203530	B1	20-03-2001	NONE			
US 5599309	A	04-02-1997	DE	69427226 D1		21-06-2001
			DE	69427226 T2		30-08-2001
			EP	0693946 A1		31-01-1996
			WO	9421316 A1		29-09-1994
US 6544234	B1	08-04-2003	DE	29801168 U1		12-08-1999
			AT	276782 T		15-10-2004
			CA	2319106 A1		29-07-1999
			DE	59812008 D1		28-10-2004
			WO	9937343 A1		29-07-1999
			EP	1452197 A2		01-09-2004
			EP	1049501 A1		08-11-2000
			JP	2002500933 T		15-01-2002